

REMARKS

In the Office Action, claims 22 and 27 are rejected under 35 U.S.C. §112, first paragraph. The Patent Office alleges that there is no clear and sufficient description in support of the claim term "ophthalmic artificial tear solution". As previously provided, claims 22 and 27 have been canceled without prejudice or disclaimer, and thus, the rejection has been rendered moot and should be withdrawn in view of same.

Further, Applicant has added new claim 30 which recites that the sterile aqueous carrier comprises an ophthalmic artificial tear solution. Applicant believes that the claim term "ophthalmic artificial tear solution" is sufficiently supported in the specification, for example, in the first paragraph of Example 2 beginning on page 18. Therefore, Applicant believes that this rejection should not be applied to new claim 30, and thus should be withdrawn.

In the Office Action, claims 19-27 are rejected under 35 U.S.C. §102 in view of U.S. Patent No. 5,252,595 (Gluchowski). As previously provided, claims 19-27 have been canceled without prejudice or disclaimer, and thus, the rejection has been rendered moot and should be withdrawn in view of same.

Further, Applicant has added new claims 28-32. Claim 28 recites an ophthalmic formulation including a sterile aqueous carrier; and a therapeutically effective amount of a pharmaceutically active compound including phentolamine, wherein the pharmaceutically active compound is capable of contracting a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision. Claims 29-32 depend from claim 28. Applicant believes that new claims 28-32 should be considered patentable over Gluchowski.

In Gluchowski, the primary emphasis relates to pharmaceutical compositions useful for reducing or maintaining intraocular pressure in animals of the mammalian species. See, Gluchowski, col. 1, lines 26-29. However, the claimed invention is directed to an ophthalmic formulation with an active phentolamine-based compound that can effectively reduce pupil size in dim light to improve vision. Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision associated with the claimed phentolamine-based formulation. See, Specification, Example 2 and Tables 1 and 2, beginning on page 18. Indeed, nowhere does Gluchowski emphasize the enhanced benefits of a phentolamine-based formulation, let alone the enhanced benefits with respect to vision by

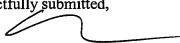
effective pupil size reduction in dim light, such as a reduction of 1.0 mm or more as further defined in claim 32. Again, Gluchowski is directed to intraocular pressure and not reduction in pupil size, let alone the reduction of pupil size in dim light to improve vision as required by the claimed invention.

Further, claim 31 recites that the phentolamine-based pharmaceutically active compound is capable of effectively reducing the pupil in dim light to improve vision and further minimizing redness to the eye. Applicant has demonstrated that the phentolamine-based formulation can provide improved vision by effective pupil size reduction in dim light while minimizing redness. See, Specification, for example, Tables 1 and 2. In Gluchowski, “[t]he primary effect on the mammal resulting from the direct administering of the active compound or compounds to the mammal’s eye is preferably a reduction in intraocular pressure.” See, Gluchowski, col. 4, lines 34-38. Moreover, nowhere does Gluchowski describe the enhanced benefit of a phentolamine-based formulation. Therefore, Applicant believes that claims 28-32 should be considered patentable for at least the reasons as discussed above.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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